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10/574,230

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Ulrike Schulz

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EXAMINER

BROOKS, KRISTIE LATRICE

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No. 10/574,230	Applicant(s) SCHULZ ET AL.	
	Examiner KRISTIE L. BROOKS	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 46-75 are new and pending.
2. Receipt and consideration of Applicants remarks filed July 29, 2009 is acknowledged.
3. Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.
4. Upon further consideration by the Examiner, the Final Rejection mailed May 29, 2009 is hereby vacated and a new non-final office action is presented below.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 55 recites "The cosmetic formulation of claim 57, where the one or more aluminum salts comprise..." It is unclear what applicant intends.

Dependent claims should depend on preceding claims (i.e. claim 54). Further, claim 57 is drawn to a ratio of (a) and (b), not aluminum salts.

For purpose of examination, the Examiner has interpreted claim 55 to depend from claim 54.

Claim Rejections – 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 46, 48 and 54-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruning et al. (US 6,942,871) in view of Yu et al. (US 5,571,841) and Niemiec et al. (US 2002/0102295).

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Applicant claims a cosmetic formulation, wherein the formulation comprises a microemulsion which comprises (a) at least one of an antiperspirant active ingredient t and (b) one or more α -hydroxycarboxylic acid which comprises mandelic acid.

Determination of the scope and content of the prior art
(MPEP 2141.01)

Bruning et al. teach a microemulsion gel composition comprising aluminum zirconium salts in the amount of 5-40% by weight, an oil component, water component, and surfactants (see the abstract, column 1 lines 63-67, column 2 lines 1-14, column 4 lines 60-67, column 7 lines 55-57, Table 1 in column 12, and claims 15-17). The formulation of the invention is transparent (see the abstract and column 2 lines 7-8). The microemulsion can contain polyethoxylated and polypropoxylated emulsifiers (see column 5 lines 29-37). The formulations may contain additional ingredients such as deodorants and α -hydroxy acids (e.g. citric acid, lactic acid, malic acid) (see column 7 lines 63-67 and column 9 lines 3-5 and lines 35-56).

Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)

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Bruning et al. teach the incorporation α -hydroxycarboxylic acids but do not teach mandelic acid. Further, Bruning et al. do not teach the instantly claimed amount of the hydroxycarboxylic acid (i.e. 0.1 to 10% by weight). These deficiencies are cured by the teachings of Yu et al. and Niemiec et al.

Yu et al. teach compositions comprising hydroxycarboxylic acids for enhancing the therapeutic effects of topically applied agents (see the abstract). Hydroxyacids are discovered to enhance the therapeutic efficacy of cosmetic agents, such as antiperspirants, when applied topically to the skin (see column 2 lines 16-40). Examples of the hydroxycarboxylic acids include mandelic acid, glycolic acid, lactic acid, etc. (see column 3 lines 11-21). The concentration of the hydroxyl acids that can be incorporated into the cosmetic formulation ranges from 0.01 to 99% by weight of the formulation (see column 6 lines 44-53). The formulations may be formulated into gels, lotion, stick, etc. (see column 6 lines 64-67).

Niemiec et al. teach compositions for application to the skin and/or hair (see the abstract). The composition may further contain benefit agents (see page 6 paragraphs 80). Examples of benefit agents include antioxidants, such as alpha hydroxy acids including mandelic acid, citric acid, glycolic acid, lactic acid, etc. (see page 7 paragraphs 87 and 88).

Finding of prima facie obviousness Rational and Motivation

(MPEP 2142-2143)

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One of ordinary skill in the art would have been motivated to incorporate mandelic acid into the microemulsion taught by Bruning because it is already known in the art that antiperspirant microemulsions can contain antioxidants such as alpha hydroxy acids, as suggested by Bruning. It is known in the art that alpha hydroxy acids such as, mandelic acid, is an antioxidant known for use in topical cosmetic formulations, as suggested by Niemeic et al. Further, Yu et al. suggest that hydroxycarboxylic acids (e.g. mandelic acid) help enhance the efficacy of antiperspirants.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate mandelic acid into the microemulsion taught by Bruning et al. because it is an obvious variation of hydroxycarboxylic acids that will not only function as an antioxidant but also enhance the efficacy of the antiperspirant in the microemulsion formulation taught by Bruning et al.

Although Bruning et al. do not teach the amount of hydroxycarboxylic acids that is present in the formulation, it would have been obvious to one of ordinary skill in the art to incorporate mandelic acid in the amount instantly claimed (i.e. 0.01 to 10% by weight) because it is known to incorporate hydroxycarboxylic acids in antiperspirant cosmetic formulations in the amount of 0.01 to 99% by weight, as suggested by Yu et al. Thus, it is an obvious amount of hydroxycarboxylic acid that may be added to antiperspirant formulations.

With respect to claims 56- 57, it is noted that the Bruning et al. and Yu et al. do not specifically teach instantly claimed ratio of (a) antiperspirant to (b)

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hydroxycarboxylic acids (i.e. (a) to b) is from 15:1 to 1:1, or 10:1 to 2.5:1).

However, Bruning et al. teach the use of antiperspirant in the amount of 5-40% by weight and Yu et al. teach that hydroxy acids can be used to enhance active compounds such as, antiperspirants, in the pharmaceutical formulations in an amount ranging from 0.01 to 99% by weight. Thus, the compounds can be used in amount that would encompass a 15:1 ratio or 1:1: ratio. For example, the antiperspirant composition can comprise 20% of antidepressant and 20% of mandelic acid. Thus, it would have been obvious for one of ordinary skill in the art to use the instant ingredients in the ratio instantly claimed. Further, It is merely routine optimization for one of ordinary skill in the art to vary the amount of antiperspirant and mandelic acid in the formulation depending on the desired properties of the formulation.

With respect to claims 61 and 62, i.e. "...wherein the formulation has a defined yield point." it is the Examiner's position that since the prior art references combined teach the combination of antiperspirants and hydroxyacids (i.e. mandelic acid), the limitation will implicitly be occur when the instant components are combined together in the composition.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

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8. Claims 47 and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruning et al. (US 6,942,871) in view of Yu et al. (US 5,571,841), Niemiec et al. (US 2002/0102295), and Diec et al. (US 6,468,551).

Applicant claims a cosmetic formulation which is based on a microemulsion and comprises (a) at least one of an antiperspirant active ingredient and a deodorant active ingredient and (b) one or more α -hydroxycarboxylic acid which comprises mandelic acid.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Bruning et al. teach a microemulsion gel composition comprising aluminum zirconium salts in the amount of 5-40%, an oil component, water component, and surfactants (see the abstract, column 1 lines 63-67, column 2 lines 1-14, column 4 lines 60-67, column 7 lines 55-57, Table 1 in column 12, and claims 15-17). The formulation of the invention is transparent (see the abstract and column 2 lines 7-8). The microemulsion can contain polyethoxylated and polypropoxylated emulsifiers (see column 5 lines 29-37). The formulations may contain additional ingredients such as deodorants and α -hydroxy acids (e.g. citric acid, lactic acid, malic acid) (see column 7 lines 63-67 and column 9 lines 3-5 and lines 35-56).

Yu et al. teach compositions comprising hydroxycarboxylic acids for enhancing the therapeutic effects of topically applied agents (see the abstract).

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Hydroxyacids are discovered to enhance the therapeutic efficacy of cosmetic agents, such as antiperspirants, when applied topically to the skin (see column 2 lines 16-40). Examples of the hydroxycarboxylic acids include mandelic acid, glycolic acid, lactic acid, etc. (see column 3 lines 11-21). The concentration of the hydroxyl acids that can be incorporated into the cosmetic formulation ranges from 0.01 to 99% by weight of the formulation (see column 6 lines 44-53). The formulations may be formulation into gels, lotion, stick, etc. (see column 6 lines 64-67).

Niemiec et al. teach compositions for application to the skin and/or hair (see the abstract). The composition may further contain benefit agents (see page 6 paragraphs 80). Examples of benefit agents include antioxidants, such as alpha hydroxy acids including mandelic acid, citric acid, glycolic acid, lactic acid, etc. (see page 7 paragraphs 87 and 88).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Bruning et al. teach a microemulsion antiperspirant gel comprising a oil component, water and emulsifiers, but do not specifically teach a oil-in-water microemulsion which comprises an oil phase, a water phase and emulsifiers. This deficiency is cured by the teachings of Diec et al.

Diec et al. teach microemulsion gels based on the oil in water type, comprising an oil phase, substantially consisting of not easily volatile

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constituents, and an aqueous phase containing one or more O/W emulsifiers free from ethylene oxide and propylene oxide and possibly one or more additional O/W emulsifiers, an emulsifier content which is lower than 20 wt. % related to the full weight of the microemulsion (see the abstract, column 7 lines 50-67 and column 8 lines 1-10). The microemulsion gel is obtained in such a way that a mixture of basic constituents, consisting of an aqueous phase, an oil phase, one or more O/W emulsifiers, possibly one or more additional O/W emulsifiers, additional or active agents, is made to react against each other in a mixing ratio so that a microemulsion can be obtained and in which droplets of discontinuous oil phase are bound to each other by one or more cross-linking substances, whose molecules are characterized by at least one hydrophylic area having a suitable expansion for bridging of distance between each microemulsion droplet and at least one hydrophobic area, which can interact hydrophobically with the microemulsion droplets(abstract, column 7 lines 50-67 and column 8 lines 1-10). It is advantageous to add W/O emulsifiers to the microemulsion gel (see column 23 lines 51-67). The microemulsion gels can be used as bases for cosmetic deodorant/antiperspirants (see column 26 lines 47-67 and column 27 lines 1-17). The microemulsion gels are stable and provide good skin tolerability (see column 4 lines 32).

Finding of prima facie obviousness Rational and Motivation**(MPEP 2142-2143)**

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One of ordinary skill in the art would have been motivated to make a oil-in-water microemulsion comprising an oil phase, water phase and an emulsifier because antiperspirant microemulsion gel comprising an oil phase, water phase and emulsifiers are known to be stable and provide good skin tolerability as suggested by Diec et al.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare in the manner taught by Diec et al. for the purpose of providing stability to the composition and enhanced benefits to the and skin.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

9. Claims 46, 54-55, 64, 66, and 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gusky et al. (US 5,776,494) in view of Bruning et al. (US 6,942,871) and Yu et al. (US 5,571,841).

Applicant claims a cosmetic formulation which is based on a microemulsion and comprises (a) at least one of an antiperspirant active ingredient and a deodorant active ingredient and (b) one or more α -hydroxycarboxylic acid which comprises mandelic acid.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Gusky et al. teach improved pharmaceutical compositions comprising antiperspirant actives (i.e. aluminum chlorohydrate, aluminum zirconium chlorohydrate, etc.) (see the abstract, column 2 lines 9-25, and column 7 lines 30-45). Other useful ingredients that can be used included are alpha hydroxy acids such as mandelic acid, lactic acid, malic acid, etc. (see column 5 lines 36-50). Mixtures of skin actives can be incorporated into the formulation (see column 7 lines 46-47). The compositions can be prepared into water-in-oil emulsions or solid emulsions (see column 14 line 66-67 and column 15 lines 1-10). The compositions can be formulated into a gel or gel stick (see column 14 lines 18-32). The Gusky et al. also teach a method for preventing perspiration and malodor associated human perspiration comprising applying to the skin a safe and effective amount of the pharmaceutical gel of the present invention (see column 17 lines 40-52).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Gusky et al. teach a pharmaceutical composition in the form of a gel or gel stick comprising an antiperspirant and mandelic acid but do not exemplify such combination. Gusky et al. further do not teach the formulation in the form of a microemulsion. These deficiencies are cured by the teachings of Bruning et al. and Yu et al.

Bruning et al. teach a microemulsion composition comprising aluminum zirconium salts in the amount of 5-40%, an oil component, water component, and surfactants (see the abstract, column 1 lines 63-67, column 2 lines 1-14, column 4 lines 60-67, column 7 lines 55-57, Table 1 in column 12, and claims 15-17). The formulation of the invention is transparent (see the abstract and column 2 lines 7-8). The microemulsion can contain polyethoxylated and polypropoxylated emulsifiers (see column 5 lines 29-37). The formulations may contain additional ingredients such as deodorants and α -hydroxy acids (e.g. citric acid, lactic acid, malic acid) (see column 7 lines 63-67 and column 9 lines 3-5 and lines 35-56). The microemulsion is useful in the production of antiperspirant gel and stick preparations (see column 1 lines 12-16 and 53-60).

Yu et al. teach compositions comprising hydroxycarboxylic acids for enhancing the therapeutic effects of topically applied agents (see the abstract). Hydroxyacids are discovered to enhance the therapeutic efficacy of cosmetic agents, such as antiperspirants, when applied topically to the skin (see column 2 lines 16-40). Examples of the hydroxycarboxylic acids include mandelic acid, glycolic acid, lactic acid, etc. (see column 3 lines 11-21). The concentration of the hydroxyl acids that can be incorporated into the cosmetic formulation ranges from 0.01 to 99% by weight of the formulation (see column 6 lines 44-53). The formulations may be formulation into gels, lotion, stick, etc. (see column 6 lines 64-67).

**Finding of prima facie obviousness Rational and Motivation
(MPEP 2142-2143)**

One of ordinary skill in the art would have been motivated to make a microemulsion comprising an antiperspirant and hydroxy acids such as mandelic acid because Gusky et al. suggest that actives such as aluminum chlorohydrate and mandelic acid can be incorporated into compositions that are useful for reducing perspiration and malodor. Further, it is known in the art that hydroxy acids such as mandelic acid can enhance the efficacy of antiperspirant actives, as suggested by Yu et al.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a microemulsion comprising an antiperspirant and mandelic acid for the purpose of providing an antiperspirant composition with enhanced benefits to the skin.

Although Gusky et al. do not teach the composition in the form of a microemulsion, it is well known in the art that compositions comprising antiperspirant and hydroxyacids can be prepared into microemulsions for the purpose of producing antiperspirant gels and sticks, as suggested by Bruning et al. Thus, it would have been obvious to one of ordinary skill in the art to prepare the instant composition as a microemulsion because it is an obvious variation of physical forms that may be used in the production of antiperspirant gels and sticks.

With respect to claim 72, it is noted that the Bruning et al. and Yu et al. do not specifically teach instantly claimed ratio of (a) antiperspirant to (b)

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hydroxycarboxylic acids (i.e. (a) to b) is from 15:1 to 1:1). However, Bruning et al. teach the use of antiperspirant in the amount of 5-40% by weight and Yu et al. teach that hydroxy acids can be used to enhance active compounds such as, antiperspirants, in the pharmaceutical formulations in an amount ranging from 0.01 to 99% by weight. Thus, the compounds can be used in amount that would encompass a 15:1 ratio or 1:1 ratio. For example, the antiperspirant composition can comprise 20% of antidepressant and 20% of mandelic acid. Thus, it would have been obvious for one of ordinary skill in the art to use the instant ingredients in the ratio instantly claimed. Further, It is merely routine optimization for one of ordinary skill in the art to vary the amount of antiperspirant and mandelic acid in the formulation depending on the desired properties of the formulation.

With respect to claims 74 and 75, i.e. "...wherein the formulation has a defined yield point." it is the Examiner's position that since the prior art references combined teach the combination of antiperspirants and hydroxyacids (i.e. mandelic acid), the instant limitations will implicitly occur when the instant components are combined together in the composition.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

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10. Claims 65 and 67-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gusky et al. (US 5,776,494) in view of Bruning et al. (US 6,942,871), Yu et al. (US 5,571,841) and Diec et al. (US 6,468,551).

Applicant claims a cosmetic formulation which is based on a microemulsion and comprises (a) at least one of an antiperspirant active ingredient and a deodorant active ingredient and (b) one or more α -hydroxycarboxylic acid which comprises mandelic acid.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Gusky et al. teach improved pharmaceutical compositions comprising antiperspirant actives (i.e. aluminum chlorohydrate, aluminum zirconium chlorohydrate, etc.) (see the abstract, column 2 lines 9-25, and column 7 lines 30-45). Other useful ingredients that can be used included are alpha hydroxy acids such as mandelic acid, lactic acid, malic acid, etc. (see column 5 lines 36-50). Mixtures of skin actives can be incorporated into the formulation (see column 7 lines 46-47). The compositions can be prepared into water-in-oil emulsions or solid emulsions (see column 14 line 66-67 and column 15 lines 1-10). The compositions can be formulated into a gel or gel stick (see column 14 lines 18-32). The Gusky et al. also teach a method for preventing perspiration and malodor associated human perspiration comprising applying to the skin a safe

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and effective amount of the pharmaceutical gel of the present invention (see column 17 lines 40-52).

Bruning et al. teach a microemulsion composition comprising aluminum zirconium salts in the amount of 5-40%, an oil component, water component, and surfactants (see the abstract, column 1 lines 63-67, column 2 lines 1-14, column 4 lines 60-67, column 7 lines 55-57, Table 1 in column 12, and claims 15-17). The formulation of the invention is transparent (see the abstract and column 2 lines 7-8). The microemulsion can contain polyethoxylated and polypropoxylated emulsifiers (see column 5 lines 29-37). The formulations may contain additional ingredients such as deodorants and α -hydroxy acids (e.g. citric acid, lactic acid, malic acid) (see column 7 lines 63-67 and column 9 lines 3-5 and lines 35-56). The microemulsion is useful in the production of antiperspirant gel and stick preparations (see column 1 lines 12-16 and 53-60).

Yu et al. teach compositions comprising hydroxycarboxylic acids for enhancing the therapeutic effects of topically applied agents (see the abstract). Hydroxyacids are discovered to enhance the therapeutic efficacy of cosmetic agents, such as antiperspirants, when applied topically to the skin (see column 2 lines 16-40). Examples of the hydroxycarboxylic acids include mandelic acid, glycolic acid, lactic acid, etc. (see column 3 lines 11-21). The concentration of the hydroxyl acids that can be incorporated into the cosmetic formulation ranges from 0.01 to 99% by weight of the formulation (see column 6 lines 44-53). The

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formulations may be formulation into gels, lotion, stick, etc. (see column 6 lines 64-67).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Gusky et al and Bruning et al. combined teach a pharmaceutical composition comprising an antiperspirant and mandelic acid can be prepared into a microemulsion but do not teach an oil-in-water microemulsion which comprises an oil phase, a water phase and emulsifiers. This deficiency is cured by the teachings of Diec et al.

Diec et al. teach microemulsion gels based on the oil in water type, comprising an oil phase, substantially consisting of not easily volatile constituents, and an aqueous phase containing one or more O/W emulsifiers free from ethylene oxide and propylene oxide and possibly one or more additional O/W emulsifiers, an emulsifier content which is lower than 20 wt. % related to the full weight of the microemulsion (see the abstract, column 7 lines 50-67 and column 8 lines 1-10). The microemulsion gel is obtained in such a way that a mixture of basic constituents, consisting of an aqueous phase, an oil phase, one or more O/W emulsifiers, possibly one or more additional O/W emulsifiers, additional or active agents, is made to react against each other in a mixing ratio so that a microemulsion can be obtained and in which droplets of discontinuous oil phase are bound to each other by one or more cross-linking substances, whose molecules are characterized by at least one hydrophylic area having a

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suitable expansion for bridging of distance between each microemulsion droplet and at least one hydrophobic area, which can interact hydrophobically with the microemulsion droplets(abstract, column 7 lines 50-67 and column 8 lines 1-10). It is advantageous to add W/O emulsifiers to the microemulsion gel (see column 23 lines 51-67). The microemulsion gels can be used as bases for cosmetic deodorant/antiperspirants (see column 26 lines 47-67 and column 27 lines 1-17). The microemulsion gels are stable and provide good skin tolerability (see column 4 lines 32).

**Finding of prima facie obviousness Rational and Motivation
(MPEP 2142-2143)**

One of ordinary skill in the art would have been motivated to make a oil-in-water microemulsion comprising an oil phase, water phase and an emulsifier because antiperspirant microemulsion gel comprising an oil phase, water phase and emulsifiers are known to be stable and provide good skin tolerability as suggested by Diec et al.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare in the manner taught by Diec et al. for the purpose of providing stability to the composition and enhanced benefits to the and skin.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as

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evidenced by the reference, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed July 29, 2009 have been fully considered but they are not persuasive.

Applicant argues that there is no motivation for one of ordinary skill in the art to use mandelic acid as an antioxidant in the preparations of Bruning et al.

These arguments are not persuasive. As stated above in the 103 rejection, mandelic acid is a known antioxidant, as suggested by Niemiec et al. Further, mandelic acid is known to enhance the therapeutic effect of antiperspirant compounds, as suggested by Yu et al. Thus, there is motivation for one of ordinary skill in the art to substitute incorporate mandelic acid into the formulations taught by Bruning et al. because it is an obvious variation of hydroxy acids that can be used as an antioxidant in topical antiperspirant formulations. Furthermore, it can enhance the therapeutic efficacy of the antiperspirant, which is extremely beneficial to actives that are topically applied to the skin since it can enhance the effectiveness of the antiperspirant.

Applicant further argues that Yu et al. teach that the property of mandelic acid is its ability to visibly reduce human skin wrinkles, not for use in underarm products.

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Moreover, Yu et al. do teach that one of the additional benefits of some hydroxy acids is to reduce visible wrinkles on the skin. However, it should be clearly understood that the disclosure of Yu et al. is drawn enhancing the therapeutic effects of topically applied active agents, including antiperspirants (see the abstract, and column 2 lines 16-40, column 3 lines 43-53, and column 18 lines 63-67).

Applicant also argues that Yu et al. do not convey that mandelic acid is a particularly desirable hydroxy acid. Applicant argues that Yu et al. do not use mandelic acid in the examples and neither does the list of 30 representative hydroxy acids in column 6.

This argument is not persuasive. Although mandelic acid is not disclosed in the examples, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments (*In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)). Further, although mandelic acid is not present in the 30 representative hydroxy acids in column 6, the representative list is not drawn to a preferred list of compounds. The list is describing hydroxy acids that can be used alone in the treatment of cosmetic or dermatological conditions (see column 6 lines 19-40). Thus, Yu et al. do not teach that mandelic acid is not a desirable compound to use, as purported by applicant.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 46, 54, 55-61, 63-64, and 72-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-57 of copending Application No. 10/574231, in view of Bruning et al. US Patent No. 6,942,871.

The instant claims are drawn to a cosmetic formulation comprising a microemulsion comprising (a) one or more antiperspirant active ingredients and (b) one or more α -hydroxycarboxylic acids which comprise mandelic acid.

Claims 34-57 of copending application No. 10/571231 are drawn to a cosmetic formulation comprising a microemulsion comprising (a) one or more antiperspirant active ingredients and (b) one or more α -hydroxycarboxylic acids which comprise mandelic acid.

Bruning et al. teach a microemulsion composition comprising aluminum zirconium salts in the amount of 5-40%, an oil component, water component, and surfactants (see the abstract, column 1 lines 63-67, column 2 lines 1-14, column 4 lines 60-67, column 7 lines 55-57, Table 1 in column 12, and claims 15-17). The formulation of the invention is transparent (see the abstract and column 2 lines 7-8). The microemulsion can contain polyethoxylated and polypropoxylated emulsifiers (see column 5 lines 29-37). The formulations may contain additional ingredients such as deodorants and α -hydroxy acids (e.g. citric acid, lactic acid, malic acid) (see column 7 lines 63-67 and column 9 lines 3-5 and lines 35-56). The microemulsion is useful in the production of antiperspirant gel and stick preparations (see column 1 lines 12-16 and 53-60).

Although the conflicting claims are not identical, they are not patentably distinct from each other because each invention is drawn to cosmetic formulations that comprise antiperspirants and mandelic acid. The instant claims differ from the copending claims by more narrowly defining the physical form of instant composition (i.e. microemulsion). However, it known in the art that cosmetic antiperspirant formulations can be prepared in the form of a

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microemulsion, which is useful for the production of antiperspirant gels or sticks, as suggested by Bruning et al. Thus, it would have been obvious to one of ordinary skill in the art to prepare cosmetic formulations in the form of a microemulsion depending on the desired final form of the product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB

/John Pak/
Primary Examiner, Art Unit 1616